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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/635,091

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Anne M. Pianca

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Boston Scientific Neuromodulation Corp.
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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

09/29/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/635,091	Applicant(s) PIANCA ET AL.	
	Examiner MICHAEL KAHRELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,10-19,22,23 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,10-13,22,23 and 28-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/5/2010 has been entered.

Claim Objections

2. Claim 1 is objected to because of the following informalities: in lines 13-14, -- having-- should be inserted between "inner core" and "a solid annular cross-section." Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4, 6, 10-13, 22, 23, and 28-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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5. In regards to claim 1, the examiner was unable to find written description support for a rounded tip that is isodiametric with the distal end of the body. Figure 2 shows distal tip 40 and paragraph 0045 indicates that the system may comprise a rounded distal tip glued or welded to the body. However, without an indication in Figure 2 of where the border is between the body and the attached tip, the examiner's position is that no support exists for a tip whose proximal end is isodiametric with the body because the tip could be coupled to the body at a point where the body has already started its distal decrease in diameter.

6. In regards to claim 31, while the examiner was able to find support for an outer cover including materials from the first clause of the claim and an inner core comprising material from the second clause of the claim, the examiner was unable to find support for the opposite arrangement, which is included within the scope of the claims. Furthermore, the examiner was unable to find support for an outer covering comprising metal (as required by claim 1) *and* the materials from the second clause (all non-metals), which is also included within the scope of this claim.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 requires that the outer covering is a metal, while claim 31 includes within its scope an outer covering that is required to be a non-metal. These limitations appear to be mutually exclusive, and thus unclear.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 2, 6, 10, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noone et al. (US 5,916,178, hereinafter "Noone") in view of Fields et al. (US 5,357,961, hereinafter "Fields").

12. In regards to claim 1, Noone discloses a stylet comprising an isodiametric elongated body (25 and 30; abstract); a rounded tip glued or welded directly to the distal end of the body such that a proximal end of the tip is isodiametric with the distal end of the body (40 and col. 5, lines 11-19); wherein the body comprises an outer covering that is a metal tube having a solid annular cross-section (30; Fig. 1); wherein the body comprises a solid inner core made of inner core material, the inner core inside the outer

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covering and having a solid annular cross-section (25 at, e.g., 70); and wherein the outer and inner core material have different elastic and buckling properties (col. 3, lines 32-36 and col. 4, line 10). Noone does not expressly disclose that the stylet comprises a handle disposed at the proximal end of the body having a larger outer diameter than the body. However, Fields teaches that it is known to provide stylets with handles disposed at the proximal end of stylet bodies having a larger outer diameter than the body (Fig. 2, elements 35 and 38) to provide the predictable results of easier handling which reduces the time it takes to fix a catheter device (col. 5, lines 1-6). Therefore, it would have been obvious to one having ordinary skill in the art to modify Noone as taught by Fields to provide the predictable results of easier handling which reduces the time it takes to fix a catheter device.

13. In regards to claim 2, the outer material is nitinol and the inner core is stainless steel (col. 3, lines 33-36 and col. 4, line 10), which are disclosed by Applicant as possessing the claimed properties.

14. In regards to claim 6, the stylet is isodiametric and the inner core has a variable diameter (Fig. 1).

15. In regards to claim 10, the inner core has a substantially constant thickness along the length of the stylet (the length 65) and the outer covering has substantially constant thickness along the same length.

16. In regards to claim 22, the inner core increases in diameter from the proximal end to the distal end (80), or vice versa (Fig. 1).

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17. In regards to claim 23, the stylet has a solid lateral cross section along the length of the body (length 90).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 3, 4, 11-13, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noone and Fields, as applied to claims 1 and 2 above, and further in view of Reynolds et al. (US 7,074,197, hereinafter "Reynolds"). Noone discloses the essential features of the claimed invention including an outer covering of polyurethane (col. 4, line 1) a preformed rod made of stainless steel (col. 4, lines 9-39), but does not expressly disclose that the stainless steel is one of the claimed alloys; an inner core made of nitinol; outer covering made of the claimed stainless steel alloys; or an inner

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core that that has been pre-stressed to operate on the compression side of the stress-strain curve. However, Reynolds teaches a means for attaching two different metals of a composite stylet structure (Fig. 2) comprising an inner core made of nitinol (26; col. 3, lines 51-60); outer covering made of the claimed stainless steel alloys (combined structure of 24 and 18; col. 3, line 44); and an inner core that that has been pre-stressed to operate on the compression side of the stress-strain curve (col. 4, lines 3-29) to provide the predictable result of providing the desired mechanical characteristics for “pushability” through the tortuous anatomy with materials having known biocompatibility and favorable material properties for stylet construction. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Noone’s invention by providing a stylet having an inner core made of nitinol, outer covering made of the claimed stainless steel alloys, and an inner core that that has been pre-stressed to operate on the compression side of the stress-strain curve to provide the predictable result of providing the desired mechanical characteristics for “pushability” through the tortuous anatomy with materials having known biocompatibility and favorable material properties for stylet construction.

21. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Noone and Fields, as applied to claim 1 above, and further in view of Ferrera (US 6,165,140, hereinafter “Ferrera”). Noone’s modified invention discloses the essential features of the claimed invention except for an outer covering that is thinner at the distal end than the proximal end of the stylet. However, Ferrera teaches that it is known in the art to provide stiffening members such as Noone’s with an outer covering that is thinner at the

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distal end than the proximal end of the stylet (36) to provide the predictable results of providing a transition in stiffness along the stylet and thus improve steerability (col. 2, line 16). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Noone's invention as taught by Ferrera by providing an outer covering that is thinner at the distal end than the proximal end of the stylet to provide the predictable results of providing a transition in stiffness along the stylet and thus improve steerability.

22. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noone and Fields as applied to claims 1 and 2 above, and further in view of Leary (US 4,545,390, hereinafter "Leary"). Noone's modified invention discloses the essential features of the claimed invention except for a stylet with a pre-formed bend or an inner core made of tungsten and platinum. However, Leary teaches that it is known to provide stylets with a pre-formed bend and made of tungsten and platinum to provide the predictable results of allowing a surgeon to manually bend the stiffening member and have it retain its shape to assist in steering the device to the desired location (col. 6, lines 32-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Noone's invention as taught by Leary by providing a stylet with a pre-formed bend and an inner core made of tungsten and platinum to provide the predictable results of allowing a surgeon to manually bend the stiffening member and have it retain its shape to assist in steering the device to the desired location.

Response to Arguments

23. Applicant's arguments with respect to claims 1-4, 6, 10-13, 22, 23, and 28-31 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762